

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2001 list were published in the Federal Register in May 2001.

New Approvals

NADA Number: 140-942

Trade Name: Maxiban[®] plus Flavomycin[®]
Ingredients: Narasin and nicarbazin, bambermycins
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: March 8, 2001
Status: Over-the-counter
Route: Oral
Species: Chickens (broiler)
Drug Form: Type A Medicated Articles to make three-way combination Type C medicated feeds.
Concentration: Narasin and nicarbazin: 36 grams each of narasin and nicarbazin activity per pound of Type A Medicated Article.
Bambermycins: 2, 4, or 10 grams bambermycins activity per pound of Type A Medicated Article.
Indications: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima* and for increased rate of weight gain and improved feed efficiency.
Tolerance: 21CFR 556.428 Narasin: The tolerance for parent narasin (the marker residue) is 480 parts per billion in the abdominal fat of chickens. The Acceptable Daily Intake (ADI) for total residues of narasin is 5 micrograms per kilogram of body weight per day.
21CFR 556.445 Nicarbazin: A tolerance of 4 parts per million is established for residues of nicarbazin in uncooked chicken muscle, liver, skin, and kidney.
Bambermycins: Tolerances are not required.
Withdrawal: 5 days

21CFR 558.95 and 558.363

NADA Number: 141-083

Trade Name: Avatec[®] plus Baciferm[®]
Ingredients: Lasalocid sodium, bacitracin zinc
Sponsor: Alpharma, Inc.
Approval Date: April 18, 2001
Status: Over-the-counter
Route: Oral
Species: Chickens (broiler)
Drug Form: Type A Medicated Articles to make Type C medicated feeds.
Concentration: Lasalocid sodium: 90.7 grams lasalocid activity per pound of Type A Medicated Article.
Bacitracin zinc: 50 grams bacitracin activity per pound of Type A Medicated Article.
Indications: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency.
Tolerance: 21CFR 556.347 Lasalocid: An ADI of 0.01 milligram per kilogram of body weight per day for lasalocid is established. A tolerance is established for residues of 1.2 parts per million for parent lasalocid in skin with adhering fat (target tissue) and 0.4 part per million in liver.
21CFR 556.70 Bacitracin: Tolerances for residues of bacitracin in uncooked edible tissues and eggs of chickens are established at 0.5 part per million. The acceptable daily intake for total residues of bacitracin is 0.05 milligram per kilogram of body weight per day.
Withdrawal: Zero days

21CFR 558.311

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Supplemental Approvals

NADA Number: 118-980

This supplemental application provides for establishing a tolerance for residues of narasin in edible tissues of chickens.

Trade Name: Monteban®
Ingredients: Narasin
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: April 11, 2001
Status: Over-the-counter
Route: Oral
Species: Chickens (broiler)
Drug Form: Type A Medicated Article
Concentration: 36, 45, 54, 72, or 90 grams of narasin activity per pound of Type A Medicated Article
Indications: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.
Tolerance: 21CFR 556.428 Narasin: The tolerance for parent narasin (the marker residue) is 480 parts per billion in the abdominal fat of chickens. The ADI for total residues of narasin is 5 micrograms per kilogram of body weight per day.
Withdrawal: Zero days

21CFR 556.428

NADA Number: 008-622

This supplemental application provides for a revised withdrawal time of oxytetracycline hydrochloride soluble powder in drinking water of swine.

Trade Name: Terramycin®, Terramycin -343®
Ingredients: Oxytetracycline hydrochloride
Sponsor: Pfizer Inc.
Approval Date: April 25, 2001
Status: Over-the-counter
Route: Oral
Drug Form: Powder
Withdrawal: Zero days

21CFR 520.1660d

Withdrawals

NADA Number: 012-585

Trade Name: Tylan Injectable
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Date: May 14, 2001

NADA Number: 015-207

Trade Name: Hyferdex Injection
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Date: May 14, 2001

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NADA Number: 030-330

Trade Name: Tylocine Sulfa Tablets
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Date: May 14, 2001

NADA Number: 031-962

Trade Name: Tylan plus Neomycin Eye Powder
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Date: May 14, 2001

NADA Number: 040-123

Trade Name: Toptic Ointment
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Date: May 14, 2001

NADA Number: 042-889

Trade Name: Oxytocin Injection
Sponsor: Veterinary Laboratories, Inc.
Date: May 14, 2001

NADA Number: 044-585

Trade Name: Oxytocin Injection
Sponsor: Steris Laboratories, Inc.
Date: May 21, 2001

NADA Number: 045-578

Trade Name: Lidocaine Hydrochloride with Epinephrine Injection 2%
Sponsor: Steris Laboratories, Inc.
Date: May 21, 2001

NADA Number: 045-737

Trade Name: Sodium Pentobarbital Injection
Sponsor: Steris Laboratories, Inc.
Date: May 21, 2001

NADA Number: 045-848

Trade Name: Phenylbutazone Injection
Sponsor: Steris Laboratories, Inc.
Date: May 21, 2001

NADA Number: 047-092

Trade Name: Tribodine
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Date: May 14, 2001

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NADA Number: 047-353

Trade Name: Ferti-Cept
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Date: May 14, 2001

NADA Number: 048-915

Trade Name: Purina Bot Control
Sponsor: Purina Mills, Inc.
Date: May 21, 2001

NADA Number: 092-602

Trade Name: Cephalothin Discs
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Date: May 14, 2001

NADA Number: 093-518

Trade Name: Tylan 10 Plus
Sponsor: Bioproducts, Inc.
Date: May 14, 2001

NADA Number: 096-162

Trade Name: Hog Grow-R-Mix-4000, Hog Grow-R-Mix-800
Sponsor: Young's, Inc.
Date: May 14, 2001

NADA Number: 096-678

Trade Name: Tribodine Capsules
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Date: May 14, 2001

NADA Number: 097-567

Trade Name: Tylan 10 Premix
Sponsor: Golden Sun Feeds, Inc.
Date: May 21, 2001

NADA Number: 097-615

Trade Name: Swine Med-A-Mix TS 8000 Premix; Tylan 5, 10, 20, 40 Sulfa-G
Sponsor: Golden Sun Feeds, Inc.
Date: May 21, 2001

NADA Number: 110-349

Trade Name: Dexamethasone Injection
Sponsor: Steris Laboratories, Inc.
Date: May 21, 2001

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NADA Number: 110-440

Trade Name: Hygromix, Hygrowormer, Hyanthelmix
Sponsor: Quali-Tech Products, Inc.
Date: May 21, 2001

NADA Number: 110-350

Trade Name: Dexamethasone Injection
Sponsor: Steris Laboratories, Inc.
Date: May 21, 2001

NADA Number: 116-196

Trade Name: Webel Tylan Premix
Sponsor: Webel Feeds, Inc.
Date: May 14, 2001

NADA Number: 117-973

Trade Name: Prednisolone Sodium Succinate for Injection
Sponsor: Steris Laboratories, Inc.
Date: May 21, 2001

Correction of Final Rules

FDA has found that the April 1, 2000, edition of Title 21, Parts 500 to 599 of the Code of Federal Regulations (CFR) does not reflect revised assay limits for Type A medicated articles containing monensin, or sulfadimethoxine and ormetoprim in combination, that were approved in the new animal drug applications for these drugs. At this time, FDA is amending the regulations to correct these errors in 21 CFR 558.4. Section 558.4 'Requirement of a medicated feed mill license' is amended in paragraph (d) in the "Category I" table in the entry for "Monensin" in the "Assay limits percent type A" column by removing "090-110" and adding in its place "085-115"; and in the "Category II" table in both paired entries for "Sulfadimethoxine" and "Ormetoprim" in the "Assay limits percent type A" column by removing "095-115" and in its place adding "090-110". This rule is effective May 2, 2001.

FDA has found several errors in the agency's regulations concerning approval of animal drugs, feeds, and related products including the list of sponsors of approved applications. To correct those errors, FDA is amending 21 CFR 510.600(c)(1) and (c)(2) to remove 28 sponsor names and their corresponding drug labeler codes (DLCs) because the firms are no longer the holders of any approved NADAs. Section 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications is amended in the table in paragraph (c)(1) by removing the entries for "Albion Laboratories, Inc.", "Balfour Guthrie & Co.", "Diamond Shamrock Corp.", "DuPont Merck Pharmaceutical Co.", "Farmers Feed & Supply Co.", "Franklin Laboratories, Inc.", "Gland-O-Lac Co.", "Michael Gordon, Inc.", "Henwood Feed Additives", "Heska Corp.", "Hubbard Milling Co.", "Lemmon Co.", "Mattox & Moore, Inc.", "McClellan Laboratories, Inc.", "Nixon and Co.", "Osborn Laboratories, Inc.", "Peter Hand Foundation", "Premier Malt Products, Inc.", "Protein Blenders, Inc.", "The Rath Packing Co.", "Rhône Merieux Canada, Inc.", "Shell Chemical Co.", "Square Deal Fortification Co.", "Sterling Winthrop, Inc.", "Syntex Animal Health, Inc.", "V.P.O., Inc.", "Vet-A-Mix, Inc.", and "Westchester Veterinary Products, Inc.", and in the table in paragraph (c)(2) by removing the entries for "000033, 000056, 000693, 000934, 010290, 010290, 011461, 011485, 011789, 012190, 012487, 025001 026186, 027863, 028260, 032707, 033999, 036108, 043728, 043729, 043732, 043735, 043737, 043738, 043743, 043744, 047015, 049047, and 063604". This rule is effective May 3, 2001.